



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

**OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361**

**OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES**

MEMORANDUM

DATE: 12/12/2006

SUBJECT: Thifensulfuron Methyl: Acute and Chronic Dietary Exposure Assessments for the
Section 3 Registration Action on Rice and Sorghum. PP#: 4F6889

PC Code: 128845

DP Barcode: D332686

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Executive Summary

Acute and chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID, Version 2.03), which uses food consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. The analyses were performed to support Section 3 requests for tolerances for residues of thifensulfuron methyl on rice and sorghum.

Acute Dietary Exposure Results and Characterization

An acute dietary exposure analysis was performed for the population subgroup Females 13-49 only. This subgroup is the only one for which an acute dietary endpoint was identified. The analysis is based on tolerance level residues and 100% crop treated assumptions. No empirical processing factors were used. A DEEM (Version 7.81) default processing factor was used for corn syrup. For drinking water, the peak surface water concentration of 3.9 ppb was used. EFED generated this value with the FIRST Model. The population subgroup Females 13-49 utilizes 0.03% of the acute population adjusted dose (aPAD) at the 95th percentile of exposure. This risk estimate is below HED's level of concern (i.e., 100% of the aPAD).

Chronic Dietary Exposure Results and Characterization

The chronic analysis is based on the same data for food commodities as were used in the acute analysis: tolerance level residues, 100% crop treated assumptions, and a default processing factor for corn syrup. For drinking water, the chronic surface water concentration of 1.5 ppb was used. EFED generated this value with the FIRST Model. The general U.S. population and all population subgroups have risk estimates that are below HED's level of concern (i.e., 100% of the chronic population adjusted dose (cPAD)). The most highly exposed population subgroup is Children 3-5 Years which utilizes 0.9% of the cPAD. The general U.S. population utilizes 0.4% of the cPAD.

Cancer Dietary Exposure Results and Characterization

An assessment of cancer risk was not performed because thifensulfuron methyl was classified as not likely to be a human carcinogen.

I. Introduction

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which HED has concluded will result in no unreasonable adverse health effects). This dose is referred to as the population adjusted dose (PAD). The PAD is equivalent to the Reference Dose (RfD) divided by the FQPA Safety Factor.

For acute and non-cancer chronic exposures, HED is concerned when estimated dietary risk exceeds 100% of the PAD. HED is generally concerned when estimated cancer risk exceeds one in one million (i.e., the risk exceeds 1×10^{-6}). References which discuss the acute and chronic risk assessments in more detail are available on the EPA/pesticides web site: "Available Information on Assessing Exposure from Pesticides, A User's Guide," 6/21/2000, web link: http://www.epa.gov/Tedrgstr/EPA-PEST_2000/July/Day-12/6061.pdf; or see SOP 99.6 (8/20/99). The most recent dietary exposure analysis for thifensulfuron methyl was performed in June of

2004 by Sherrie Kinard as part of the tolerance reassessment eligibility decision (D299766, 6/1/2004).

II. Residue Information

Residues in Food

HED is recommending in favor of the establishment of tolerances on rice and sorghum at 0.05 ppm each. All issues and data regarding the tolerance requests are discussed in the residue chemistry summary document prepared for the requests (D330702, S. Hummel, 8/8/2006). Tolerances for thifensulfuron methyl are listed in 40CFR§180.439. The following tolerances are currently in effect: 0.1 ppm for soybeans, 0.05 ppm for barley, field corn, oats, and wheat, and 0.02 ppm for canola, cottonseed, and flax seed.

The residue chemistry summary document prepared for this tolerance petition states the following with respect to processed commodities: "Because residues of thifensulfuron methyl were below the LOQ in/on all samples of corn grain, rice grain, sorghum grain, and soybean seed following treatment at 5x the proposed maximum rate, no processing data will be required to support the proposed uses." No tolerances have been established for processed commodities. DEEM (Version 7.81) default processing factors were used for processed commodities. The only default processing factor available for any of the commodities in these analyses is that for corn syrup (1.5x).

Residues in Water

EFED provided a drinking water assessment for thifensulfuron methyl (Memo, D332797, J. Breithaupt, 10/26/2006). Estimated drinking water concentrations (EDWCs) were generated using the FIRST Model for surface water values and the SCIGROW Model for the groundwater value. The acute and chronic surface water values were 3.9 ppb and 1.5 ppb, respectively. The groundwater value was 0.27 ppb. As the surface water values were higher than the groundwater value, the surface water values were used in the assessments. A concentration of 3.9 ppb was used for the acute assessment and a concentration of 1.5 ppb was used for the chronic assessment.

III. Percent Crop Treated

For these analyses, the assumption was made that 100% of the crops with thifensulfuron methyl tolerances will be treated with thifensulfuron methyl.

IV. DEEM-FCID™ Program and Consumption Information

Thifensulfuron methyl acute and chronic dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database

(DEEM-FCID™, Version 2.03), which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The 1994-96, 98 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (e.g., apple pie) are linked to EPA-defined food commodities (e.g. apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups, but for acute exposure assessment are retained as individual consumption events. Based on analysis of the 1994-96, 98 CSFII consumption data, which took into account dietary patterns and survey respondents, HED concluded that it is most appropriate to report risk for the following population subgroups: the general U.S. population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50+ years old.

For chronic dietary exposure assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food form is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

For acute exposure assessment, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic (Tier 1 or Tier 2) exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic (Tier 3/4) assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (i.e., those who reported eating relevant commodities/food forms) and a per-capita (i.e., those who reported eating the relevant commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for all tiers of analysis. However, for Tiers 1 and 2, significant differences in user vs. per capita exposure and risk are identified and noted in the risk assessment.

V. Toxicological Information

The risk assessment team evaluated the toxicology database for thifensulfuron methyl and selected doses and endpoints for acute and chronic dietary exposure risk assessments. The acute and chronic dietary reference doses and PADs are presented in Table 1 below. The risk assessment team also evaluated the potential for increased susceptibility of infants and children from exposure to thifensulfuron methyl. The team concluded that the FQPA Safety Factor should be reduced to 1x as there are no residual uncertainties for pre and post natal toxicity.

Thifensulfuron methyl was classified as not likely to be a human carcinogen based on the lack of evidence of carcinogenicity in both the rat and the mouse; therefore, a cancer dietary exposure analysis was not performed.

Table 1. Summary of Toxicological Doses and Endpoints for Thifensulfuron Methyl for Use in Dietary Exposure Assessment			
Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA Safety Factor and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary: Females 13-49 only	Maternal NOAEL = 159 mg/kg/day UF = 100 Acute RfD = 1.59 mg/kg/day	FQPA SF = 1x cPAD = <u>chronic RfD</u> FQPA SF = 1.59 mg/kg/day	Developmental oral toxicity study in rats. Developmental LOAEL = 725 mg/kg/day, based on decreased mean body weight and increased incidence of small renal papillae.
Chronic Dietary: All populations	NOAEL = 7 mg/kg/day UF = 100 Chronic RfD = 0.07 mg/kg/day	FQPA SF = 1x cPAD = <u>chronic RfD</u> FQPA SF = 0.07 mg/kg/day	90-Day Oral Toxicity in Rat LOAEL = 177 mg/kg/day based on decreased body weight and body weight gain in both males and females, and increased spleen weights in males.
Cancer (oral, dermal, inhalation)	Thifensulfuron methyl was classified as not likely to be a human carcinogen based on the lack of evidence of carcinogenicity in both the rat and the mouse.		

VI. Results/Discussion

As stated above, for acute and chronic assessments, HED is concerned when dietary risk exceeds 100% of the PAD. The DEEM-FCID™ analyses estimate the dietary exposure of the U.S. population and various population subgroups. The results reported in Table 2 are for the population subgroup Females 13-49, and the results reported in Table 3 are for the general U.S. Population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, females 13-49, adults 20-49, and adults 50+ years.

Results of Acute Dietary Exposure Analysis

The results of the acute dietary exposure analysis at the 95th, 99th, and 99.9th percentiles of exposure are reported in Table 2. As percent crop treated estimates were not used in the assessment, HED recommends that the 95th percentile of exposure be used for regulation.

**Table 2. Results of Acute Dietary Exposure Analysis
(Food and Drinking Water)**

Population Subgroup	aPAD (mkd)*	95 th Percentile		99 th Percentile		99.9 th Percentile	
		Exposure (mkd)	% aPAD	Exposure (mkd)	% aPAD	Exposure (mkd)	% aPAD
Females 13-49 years old	1.59	0.000524	<1	0.000732	<1	0.001078	<1

*mkd: milligram per kilogram body weight per day

Results of Chronic Dietary Exposure Analysis

The summary table below lists the results of the chronic dietary exposure analysis along with the results of the acute analysis at the regulated percentile of exposure (i.e., the 95th). The acute and chronic dietary risk estimates for the general U.S. population and all population subgroups are below HED's level of concern.

**Table 3. Summary of Dietary Exposure and Risk for Thifensulfuron Methyl
(Food and Drinking Water)**

Population Subgroup*	Acute Dietary (95 th Percentile)		Chronic Dietary		Cancer	
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD	Dietary Exposure (mg/kg/day)	Risk
General U.S. Population	N/A	N/A	0.000284	<1	N/A	N/A
All Infants (<1 year old)	N/A	N/A	0.000469	<1		
Children 1-2 years old	N/A	N/A	0.000601	<1		
Children 3-5 years old	N/A	N/A	0.000621	<1		
Children 6-12 years old	N/A	N/A	0.000447	<1		
Youth 13-19 years old	N/A	N/A	0.000310	<1		
Adults 20-49 years old	N/A	N/A	0.000239	<1		
Adults 50+ years old	N/A	N/A	0.000175	<1		
Females 13-49 years old	0.000524	<1	0.000226	<1		

VII. Characterization of Inputs/Outputs

Very conservative assumptions were made in both the acute and chronic dietary exposure analyses. Residues in foods were assumed to be equivalent to the tolerance levels. Tolerance level residues should always exceed the residue levels found on food commodities at the time of consumption. When field trials are performed, the maximum allowable application rate is used and crops are harvested at the minimum PHI. Samples are stored frozen until analysis to ensure minimal degradation of residues. In actual practice, however, growers will not usually use the maximum application rates for economic reasons. In addition, most crops are not harvested and immediately stored frozen. Conservative residue values were used for drinking water as well. The surface water values used were conservative, unrefined values and were higher than the estimated groundwater concentrations that were generated. For these reasons, HED is confident that these analyses do not underestimate risk to the general U.S. population or any population subgroup.

VIII. Conclusions

Based on very conservative assumptions, the acute and chronic dietary risk estimates to thifensulfuron methyl are below HED's level of concern for the general U.S. population and all population subgroups, including those comprised of infants and children.

VIII. List of Attachments

Attachment 1: Residue Input File for Acute Analysis
Attachment 2: Results of Acute Dietary Exposure Analysis
Attachment 3: Residue Input File for Chronic Analysis
Attachment 4: Results of Chronic Dietary Exposure Analysis

cc: D. Dotson

Attachment 1: Residue Input File for Acute Analysis

DEEM-FCID Version 2.03 (1994-1998 Data)

Acute NOAEL = 159 mg/kg/day

Acute PAD = 1.59 mg/kg/day

Filename: C:\Documents and Settings\ddotson\My Documents\DEEMFCID\Thifensulfuron\ThifenAC.R98

Date created/last modified: 12-11-2006/09:59:45/8

EPA Code	Crop Grp	Commodity Name	Def Res (ppm)	Adj. Factors #1	Adj. Factors #2	Comment
06003470	6	Soybean, seed	0.100000	1.000	1.000	
06003480	6	Soybean, flour	0.100000	1.000	1.000	
06003481	6	Soybean, flour-babyfood	0.100000	1.000	1.000	
06003490	6	Soybean, soy milk	0.100000	1.000	1.000	
06003491	6	Soybean, soy milk-babyfood or in	0.100000	1.000	1.000	
06003500	6	Soybean, oil	0.100000	1.000	1.000	
06003501	6	Soybean, oil-babyfood	0.100000	1.000	1.000	
15000250	15	Barley, pearled barley	0.050000	1.000	1.000	
15000251	15	Barley, pearled barley-babyfood	0.050000	1.000	1.000	
15000260	15	Barley, flour	0.050000	1.000	1.000	
15000261	15	Barley, flour-babyfood	0.050000	1.000	1.000	
15000270	15	Barley, bran	0.050000	1.000	1.000	
15001200	15	Corn, field, flour	0.050000	1.000	1.000	
15001201	15	Corn, field, flour-babyfood	0.050000	1.000	1.000	
15001210	15	Corn, field, meal	0.050000	1.000	1.000	
15001211	15	Corn, field, meal-babyfood	0.050000	1.000	1.000	
15001220	15	Corn, field, bran	0.050000	1.000	1.000	
15001230	15	Corn, field, starch	0.050000	1.000	1.000	
15001231	15	Corn, field, starch-babyfood	0.050000	1.000	1.000	
15001240	15	Corn, field, syrup	0.050000	1.500	1.000	
15001241	15	Corn, field, syrup-babyfood	0.050000	1.500	1.000	
15001250	15	Corn, field, oil	0.050000	1.000	1.000	
15001251	15	Corn, field, oil-babyfood	0.050000	1.000	1.000	
15002310	15	Oat, bran	0.050000	1.000	1.000	
15002320	15	Oat, flour	0.050000	1.000	1.000	
15002321	15	Oat, flour-babyfood	0.050000	1.000	1.000	
15002330	15	Oat, groats/rolled oats	0.050000	1.000	1.000	
15002331	15	Oat, groats/rolled oats-babyfood	0.050000	1.000	1.000	
15003230	15	Rice, white	0.050000	1.000	1.000	
15003231	15	Rice, white-babyfood	0.050000	1.000	1.000	
15003240	15	Rice, brown	0.050000	1.000	1.000	
15003241	15	Rice, brown-babyfood	0.050000	1.000	1.000	
15003250	15	Rice, flour	0.050000	1.000	1.000	
15003251	15	Rice, flour-babyfood	0.050000	1.000	1.000	
15003260	15	Rice, bran	0.050000	1.000	1.000	
15003261	15	Rice, bran-babyfood	0.050000	1.000	1.000	
15003440	15	Sorghum, grain	0.050000	1.000	1.000	
15003450	15	Sorghum, syrup	0.050000	1.000	1.000	
15004010	15	Wheat, grain	0.050000	1.000	1.000	
15004011	15	Wheat, grain-babyfood	0.050000	1.000	1.000	
15004020	15	Wheat, flour	0.050000	1.000	1.000	
15004021	15	Wheat, flour-babyfood	0.050000	1.000	1.000	
15004030	15	Wheat, germ	0.050000	1.000	1.000	
15004040	15	Wheat, bran	0.050000	1.000	1.000	
15004050	15	Wild rice	0.050000	1.000	1.000	
20001630	20	Flaxseed, oil	0.020000	1.000	1.000	
20003190	20	Rapeseed, oil	0.020000	1.000	1.000	
20003191	20	Rapeseed, oil-babyfood	0.020000	1.000	1.000	
86010000	0	Water, direct, all sources	0.003900	1.000	1.000	
86020000	0	Water, indirect, all sources	0.003900	1.000	1.000	
95001280	0	Cottonseed, oil	0.020000	1.000	1.000	
95001281	0	Cottonseed, oil-babyfood	0.020000	1.000	1.000	

Attachment 2: Results of Acute Dietary Exposure Analysis

Acute NOAEL = 159 mg/kg/day

Acute PAD = 1.59 mg/kg/day

Residue file: ThifenAC.R98

Adjustment factor #2 NOT used.

Analysis Date: 12-11-2006/10:19:08

Residue file dated: 12-11-2006/10:14:41/8

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Summary calculations (per capita):

95th Percentile			99th Percentile			99.9th Percentile		
Exposure	% aPAD	MOE	Exposure	% aPAD	MOE	Exposure	% aPAD	MOE

Females 13-49 yrs:								
0.000524	0.03	303593	0.000732	0.05	217236	0.001078	0.07	147427

Attachment 3: Residue Input File for Chronic Analysis

DEEM-FCID Version 2.03 (1994-1998 Data)

Chronic NOAEL = 7 mg/kg/day

Chronic PAI = 0.07 mg/kg/day

Filename: C:\Documents and Settings\ddotson\My Documents\DEEMFCID\Thifensulfuron\ThifenCHR.R98

Date created last modified: 11-13-2006/13:55:06/8

EPA Code	Crop	Commodity Name	Def Res (ppm)	Adj. Factors #1	Adj. Factors #2	Comment
06003470	6	Soybean, seed	0.100000	1.000	1.000	
06003480	6	Soybean, flour	0.100000	1.000	1.000	
06003481	6	Soybean, flour-babyfood	0.100000	1.000	1.000	
06003490	6	Soybean, soy milk	0.100000	1.000	1.000	
06003491	6	Soybean, soy milk-babyfood or in	0.100000	1.000	1.000	
06003500	6	Soybean, oil	0.100000	1.000	1.000	
06003501	6	Soybean, oil-babyfood	0.100000	1.000	1.000	
15000250	15	Barley, pearled barley	0.050000	1.000	1.000	
15000251	15	Barley, pearled barley-babyfood	0.050000	1.000	1.000	
15000260	15	Barley, flour	0.050000	1.000	1.000	
15000261	15	Barley, flour-babyfood	0.050000	1.000	1.000	
15000270	15	Barley, bran	0.050000	1.000	1.000	
15001200	15	Corn, field, flour	0.050000	1.000	1.000	
15001201	15	Corn, field, flour-babyfood	0.050000	1.000	1.000	
15001210	15	Corn, field, meal	0.050000	1.000	1.000	
15001211	15	Corn, field, meal-babyfood	0.050000	1.000	1.000	
15001220	15	Corn, field, bran	0.050000	1.000	1.000	
15001230	15	Corn, field, starch	0.050000	1.000	1.000	
15001231	15	Corn, field, starch-babyfood	0.050000	1.000	1.000	
15001240	15	Corn, field, syrup	0.050000	1.500	1.000	
15001241	15	Corn, field, syrup-babyfood	0.050000	1.500	1.000	
15001250	15	Corn, field, oil	0.050000	1.000	1.000	
15001251	15	Corn, field, oil-babyfood	0.050000	1.000	1.000	
15002310	15	Oat, bran	0.050000	1.000	1.000	
15002320	15	Oat, flour	0.050000	1.000	1.000	
15002321	15	Oat, flour-babyfood	0.050000	1.000	1.000	
15002330	15	Oat, groats/rolled oats	0.050000	1.000	1.000	
15002331	15	Oat, groats/rolled oats-babyfood	0.050000	1.000	1.000	
15003230	15	Rice, white	0.050000	1.000	1.000	
15003231	15	Rice, white-babyfood	0.050000	1.000	1.000	
15003240	15	Rice, brown	0.050000	1.000	1.000	
15003241	15	Rice, brown-babyfood	0.050000	1.000	1.000	
15003250	15	Rice, flour	0.050000	1.000	1.000	
15003251	15	Rice, flour-babyfood	0.050000	1.000	1.000	
15003260	15	Rice, bran	0.050000	1.000	1.000	
15003261	15	Rice, bran-babyfood	0.050000	1.000	1.000	
15003440	15	Sorghum, grain	0.050000	1.000	1.000	
15003450	15	Sorghum, syrup	0.050000	1.000	1.000	
15004010	15	Wheat, grain	0.050000	1.000	1.000	
15004011	15	Wheat, grain-babyfood	0.050000	1.000	1.000	
15004020	15	Wheat, flour	0.050000	1.000	1.000	
15004021	15	Wheat, flour-babyfood	0.050000	1.000	1.000	
15004030	15	Wheat, germ	0.050000	1.000	1.000	
15004040	15	Wheat, bran	0.050000	1.000	1.000	
15004050	15	Wild rice	0.050000	1.000	1.000	
20001630	20	Flaxseed, oil	0.020000	1.000	1.000	
20003190	20	Rapeseed, oil	0.020000	1.000	1.000	
20003191	20	Rapeseed, oil-babyfood	0.020000	1.000	1.000	
86010000	0	Water, direct, all sources	0.001500	1.000	1.000	
86020000	0	Water, indirect, all sources	0.001500	1.000	1.000	
95001140	0	Cottonseed, oil	0.020000	1.000	1.000	
95001141	0	Cottonseed, oil-babyfood	0.020000	1.000	1.000	

Attachment 4: Results of Chronic Dietary Exposure Analysis

DEEM-FCID Version 2.03 (1994-1998 Data)

Chronic NOAEL = 7 mg/kg/day

Chronic PAD = 0.07 mg/kg/day

Residue file name: C:\Documents and Settings\ddotson\My

Documents\DEEMFCID\Thifensulfuron\ThifenCHR.R98

Analysis Date 12-11-2006/10:20:04

Residue file dated: 12-11-2006/10:15:37/8

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Total exposure by population subgroup

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Percent of PAD
U.S. Population (total)	0.000284	0.4%
U.S. Population (spring season)	0.000287	0.4%
U.S. Population (summer season)	0.000288	0.4%
U.S. Population (autumn season)	0.000279	0.4%
U.S. Population (winter season)	0.000281	0.4%
Northeast region	0.000273	0.4%
Midwest region	0.000296	0.4%
Southern region	0.000274	0.4%
Western region	0.000298	0.4%
Hispanics	0.000307	0.4%
Non-hispanic whites	0.000276	0.4%
Non-hispanic blacks	0.000291	0.4%
Non-hisp/non-white/non-black	0.000335	0.5%
All infants (< 1 year)	0.000469	0.7%
Nursing infants	0.000178	0.3%
Non-nursing infants	0.000580	0.8%
Children 1-5 yrs	0.000602	0.9%
Children 6-12 yrs	0.000429	0.6%
Females 13-19 (not preg or nursing)	0.000270	0.4%
Females 20+ (not preg or nursing)	0.000196	0.3%
Females 13-59 yrs	0.000239	0.3%
Females 13+ (preg/not nursing)	0.000244	0.3%
Females 13+ (nursing)	0.000261	0.4%
Males 13-19 yrs	0.000348	0.5%
Males 20+ yrs	0.000236	0.3%
Seniors 65+	0.000170	0.2%
Children 1-2 yrs	0.000601	0.9%
Children 3-5 yrs	0.000621	0.9%
Children 6-12 yrs	0.000447	0.6%
Youth 13-19 yrs	0.000310	0.4%
Adults 20-49 yrs	0.000239	0.3%
Adults 50+ yrs	0.000175	0.2%
Females 13-49 yrs	0.000226	0.3%



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

**OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES**

MEMORANDUM DRAFT

DATE: 12/6/2006

SUBJECT: Tribenuron Methyl: Chronic Dietary Exposure Assessment for the Section 3
Registration Action on Field Corn, Rice, Sorghum, Soybeans, (PP# 4F6890) and
Sunflowers (PP# 4E6855).

PC Code: 128887

DP Barcode: D332685

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Executive Summary

A chronic dietary risk assessment was conducted using the Dietary Exposure Evaluation Model (DEEM-FCID, Version 2.03), which uses food consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. The analysis was performed to support Section 3 requests for tolerances for residues of tribenuron methyl on field corn, rice, sorghum, soybeans, and sunflowers.

Acute Dietary Exposure Results and Characterization

An acute dietary exposure analysis was not performed because no acute endpoint was identified.

Chronic Dietary Exposure Results and Characterization

The chronic dietary exposure analysis is based on tolerance level residues and 100% crop treated assumptions. No empirical processing factors were used. A DEEM (Version 7.81) default processing factor was used for corn syrup. For drinking water, the groundwater concentration of 6.8 ppb was used. EFED generated this value with the SCIGROW Model. The general U.S. population and all population subgroups have risk estimates that are below HED's level of concern (i.e., 100% of the chronic population adjusted dose (cPAD)). The most highly exposed population subgroup is All Infants (< 1 year old) which utilizes 9.8% of the cPAD. The general U.S. population utilizes 4.7% of the cPAD.

Cancer Dietary Exposure Results and Characterization

Tribenuron methyl is classified as a possible human carcinogen. A separate assessment of cancer risk was not necessary, however, because the chronic dietary risk assessment is protective of any potential risk of carcinogenicity.

I. Introduction

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which HED has concluded will result in no unreasonable adverse health effects). This dose is referred to as the population adjusted dose (PAD). The PAD is equivalent to the Reference Dose (RfD) divided by the FQPA Safety Factor.

For acute and non-cancer chronic exposures, HED is concerned when estimated dietary risk exceeds 100% of the PAD. HED is generally concerned when estimated cancer risk exceeds one in one million (i.e., the risk exceeds 1×10^{-6}). References which discuss the acute and chronic risk assessments in more detail are available on the EPA/pesticides web site: "Available Information on Assessing Exposure from Pesticides, A User's Guide," 6/21/2000, web link: http://www.epa.gov/fedrgsr/EPA-PEST/2000_July-Day-12/6061.pdf; or see SOP 99.6 (8/20/99).

The most recent dietary exposure analysis for tribenuron methyl was performed in support of the tolerance reassessment eligibility decision (TRED) for tribenuron (D301595, R. Griffin, 6/23/2004).

II. Residue Information

Residues in Food

HED is recommending in favor of the establishment of tolerances on field corn, rice, sorghum, soybeans, and sunflower seeds at 0.05 ppm each. All issues and data regarding the tolerance requests are discussed in the residue chemistry summary document prepared for the requests (D330633, S. Hummel, 8/8/2006). Tolerances for tribenuron methyl are listed in 40CFR§180.451. The following tolerances are currently in effect: 0.05 ppm for barley, oats, and wheat, and 0.02 ppm for canola, cottonseed, and flax seed.

The residue chemistry summary document prepared for this tolerance petition states the following with respect to processed commodities: "Because residues of tribenuron methyl were below the LOQ in/on all samples of corn grain, rice grain, sorghum grain, soybean seed, and sunflower seed following treatment at 5x the proposed maximum seasonal rate, no processing data will be required to support the proposed uses." No tolerances have been established for processed commodities. DEEM (Version 7.81) default processing factors were used for processed commodities. The only default processing factor available for any of the commodities in this analysis is that for corn syrup (1.5x).

Residues in Water

EFED provided a drinking water assessment for tribenuron methyl (Memo, D332797, J. Breithaupt, 10/26/2006). Estimated drinking water concentrations (EDWCs) were generated using the FIRST Model for surface water values and the SCIGROW Model for groundwater values. The acute and chronic surface water values were 4.1 ppb and 2.7 ppb, respectively. The groundwater value was 6.8 ppb. As the groundwater value was higher than the surface water values, the groundwater value was used in the assessment.

III. Percent Crop Treated

For these analyses, the assumption was made that 100% of the crops with tribenuron methyl tolerances will be treated with tribenuron methyl.

IV. DEEM-FCID™ Program and Consumption Information

A tribenuron methyl chronic dietary exposure assessment was conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03), which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The 1994-96, 98 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (e.g., apple pie) are linked to EPA-defined food commodities (e.g. apples,

peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups, but for acute exposure assessment are retained as individual consumption events. Based on analysis of the 1994-96, 98 CSFII consumption data, which took into account dietary patterns and survey respondents, HED concluded that it is most appropriate to report risk for the following population subgroups: the general U.S. population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50+ years old.

For chronic dietary exposure assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food form is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

V. Toxicological Information

For this dietary exposure analysis, the same doses and endpoints were used that were used in the TRED of 2004. A discussion of the toxicology and endpoint selection for tribenuron methyl can be found in the TRED document (D301595, R. Griffin, 6/23/2004). The chronic dietary reference dose and PAD are presented in Table 1 below. The FQPA Safety Factor was reduced to 1x. The toxicology database for tribenuron methyl is adequate for FQPA considerations. There is low concern for pre- and/or post-natal toxicity resulting from exposure to tribenuron methyl. The available data from the developmental and reproductive toxicity studies do not indicate a potential susceptibility of infants and children to tribenuron methyl.

Tribenuron methyl is classified as a possible human carcinogen. A separate assessment of cancer risk is not necessary, however, because the chronic dietary risk assessment is protective of any potential risk of carcinogenicity.

Table 1. Summary of Toxicological Doses and Endpoints for Tribenuron Methyl for Use in Dietary Exposure Assessment			
Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA Safety Factor and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary: All Population	No acute endpoint identified.	N/A	N/A
Chronic Dietary: All populations	NOAEL = 0.8 mg/kg/day UF = 100 Chronic RfD = 0.008 mg/kg/day	FQPA SF = 1X cPAD = cRfD ÷ FQPA SF = 0.008 mg/kg/day	Chronic Dog LOAEL = 8.2 mg/kg/day (in males) based on elevated bilirubin, AST, increased urinary volume, and 20% reduction in body weight gain.
Cancer (oral, dermal, inhalation)	Tribenuron methyl is classified as a possible human carcinogen. A separate assessment of cancer risk is not necessary, however, because the chronic dietary risk assessment is protective of any potential risk of carcinogenicity.		

NOAEL: No observable adverse effect level, UF: uncertainty factor, LOAEL: lowest observable adverse effect level, cRfD: chronic reference dose

VI. Results/Discussion

As stated above, for chronic assessments, HED is concerned when dietary risk exceeds 100% of the PAD. The DEEM-FCID™ analyses estimate the dietary exposure of the U.S. population and various population subgroups. The results reported in Table 2 are for the general U.S. Population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, females 13-49, adults 20-49, and adults 50+ years. The chronic dietary risk estimates for the general U.S. population and all population subgroups are below HED's level of concern.

**Table 2. Summary of Dietary Exposure and Risk for Tribenuron Methyl
(Food and Drinking Water)**

Population Subgroup	Acute Dietary		Chronic Dietary		Cancer	
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD	Dietary Exposure (mg/kg/day)	Risk
General U.S. Population	N/A	N/A	0.000373	4.7	The chronic analysis is protective of cancer effects	
All Infants (< 1 year old)	N/A	N/A	0.000784	9.8		
Children 1-2 years old	N/A	N/A	0.000715	8.9		
Children 3-5 years old	N/A	N/A	0.000725	9.1		
Children 6-12 years old	N/A	N/A	0.000518	6.5		
Youth 13-19 years old	N/A	N/A	0.000367	4.6		
Adults 20-49 years old	N/A	N/A	0.000325	4.1		
Adults 50+ years old	N/A	N/A	0.000270	3.4		
Females 13-49 years old	N/A	N/A	0.000312	3.9		

VII. Characterization of Inputs/Outputs

Very conservative assumptions were made in this chronic dietary exposure analysis. Residues in foods were assumed to be equivalent to the tolerance levels. Tolerance level residues should always exceed the residue levels found on food commodities at the time of consumption. When field trials are performed, the maximum allowable application rate is used and crops are harvested at the minimum PHI. Samples are stored frozen until analysis to ensure minimal degradation of residues. In actual practice, however, growers will not usually use the maximum application rates for economic reasons. In addition, most crops are not harvested and immediately stored frozen. A conservative residue value was used for drinking water as well. The groundwater value used was a conservative, unrefined value and was higher than the estimated surface water concentrations that were generated. For these reasons, HED is confident that this analysis does not underestimate dietary risk to the general U.S. population or any population subgroup.

VIII. Conclusions

Based on very conservative assumptions, the chronic dietary risk estimates to tribenuron methyl are below HED's level of concern for the general U.S. population and all population subgroups, including those comprised of infants and children.

VIII. List of Attachments

Attachment 1: Residue Input File for Chronic Analysis

Attachment 2: Results of Chronic Dietary Exposure Analysis

cc: D. Dotson

Attachment 1: Residue Input File for Chronic Analysis

DEEM-FCID Version 2.03 (1994-1998 data)

Chronic NOAEL = 0.8 mg/kg/day

Chronic PAD = 0.008 mg/kg/day

Date created/last modified: 11-13-2006/10:37:41/8

EPA Comment Code	Crop Grp	Commodity Name	Def Res (ppm)	Adj.Factors	
				#1	#2
06003470	6	Soybean, seed	0.050000	1.000	1.000
06003480	6	Soybean, flour	0.050000	1.000	1.000
06003481	6	Soybean, flour-babyfood	0.050000	1.000	1.000
06003490	6	Soybean, soy milk	0.050000	1.000	1.000
06003491	6	Soybean, soy milk-babyfood or in	0.050000	1.000	1.000
06003500	6	Soybean, oil	0.050000	1.000	1.000
06003501	6	Soybean, oil-babyfood	0.050000	1.000	1.000
15000250	15	Barley, pearled barley	0.050000	1.000	1.000
15000251	15	Barley, pearled barley-babyfood	0.050000	1.000	1.000
15000260	15	Barley, flour	0.050000	1.000	1.000
15000261	15	Barley, flour-babyfood	0.050000	1.000	1.000
15000270	15	Barley, bran	0.050000	1.000	1.000
15001200	15	Corn, field, flour	0.050000	1.000	1.000
15001201	15	Corn, field, flour-babyfood	0.050000	1.000	1.000
15001210	15	Corn, field, meal	0.050000	1.000	1.000
15001211	15	Corn, field, meal-babyfood	0.050000	1.000	1.000
15001220	15	Corn, field, bran	0.050000	1.000	1.000
15001230	15	Corn, field, starch	0.050000	1.000	1.000
15001231	15	Corn, field, starch-babyfood	0.050000	1.000	1.000
15001240	15	Corn, field, syrup	0.050000	1.500	1.000
15001241	15	Corn, field, syrup-babyfood	0.050000	1.500	1.000
15001250	15	Corn, field, oil	0.050000	1.000	1.000
15001251	15	Corn, field, oil-babyfood	0.050000	1.000	1.000
15002310	15	Oat, bran	0.050000	1.000	1.000
15002320	15	Oat, flour	0.050000	1.000	1.000
15002321	15	Oat, flour-babyfood	0.050000	1.000	1.000
15002330	15	Oat, groats/rolled oats	0.050000	1.000	1.000
15002331	15	Oat, groats/rolled oats-babyfood	0.050000	1.000	1.000
15003230	15	Rice, white	0.050000	1.000	1.000
15003231	15	Rice, white-babyfood	0.050000	1.000	1.000
15003240	15	Rice, brown	0.050000	1.000	1.000
15003241	15	Rice, brown-babyfood	0.050000	1.000	1.000
15003250	15	Rice, flour	0.050000	1.000	1.000
15003251	15	Rice, flour-babyfood	0.050000	1.000	1.000
15003260	15	Rice, bran	0.050000	1.000	1.000
15003261	15	Rice, bran-babyfood	0.050000	1.000	1.000
15003440	15	Sorghum, grain	0.050000	1.000	1.000
15003450	15	Sorghum, syrup	0.050000	1.000	1.000
15004010	15	Wheat, grain	0.050000	1.000	1.000
15004011	15	Wheat, grain-babyfood	0.050000	1.000	1.000
15004020	15	Wheat, flour	0.050000	1.000	1.000
15004021	15	Wheat, flour-babyfood	0.050000	1.000	1.000
15004030	15	Wheat, germ	0.050000	1.000	1.000
15004040	15	Wheat, bran	0.050000	1.000	1.000
15004050	15	Wild rice	0.050000	1.000	1.000

20001630	20	Flaxseed, oil	0.020000	1.000	1.000
20003190	20	Rapeseed, oil	0.020000	1.000	1.000
20003191	20	Rapeseed, oil-babyfood	0.020000	1.000	1.000
20003640	20	Sunflower, seed	0.050000	1.000	1.000
20003650	20	Sunflower, oil	0.050000	1.000	1.000
20003651	20	Sunflower, oil-babyfood	0.050000	1.000	1.000
86010000	0	Water, direct, all sources	0.006800	1.000	1.000
86020000	0	Water, indirect, all sources	0.006800	1.000	1.000
95001280	0	Cottonseed, oil	0.020000	1.000	1.000
95001281	0	Cottonseed, oil-babyfood	0.020000	1.000	1.000

Attachment 4: Results of Chronic Dietary Exposure Analysis

DEEM-FCID Version 2.03, 1994-1998 data
Residue file name: C:\Documents and Settings\ddotson\My
Documents\DEEMFCID\Tribenuron\Tribenuron.R98
Adjustment factor #2 NOT used.

Analysis Date 11-13-2006/10:40:11 Residue file dated: 11-13-2006/10:37:41/8
Chronic PAD = 0.008 mg/kg bw/day

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Total exposure by population subgroup

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Percent of PAD
U.S. Population (total)	0.000373	4.7%
U.S. Population (spring season)	0.000375	4.7%
U.S. Population (summer season)	0.000385	4.8%
U.S. Population (autumn season)	0.000364	4.6%
U.S. Population (winter season)	0.000365	4.6%
Northeast region	0.000353	4.4%
Midwest region	0.000385	4.8%
Southern region	0.000357	4.5%
Western region	0.000402	5.0%
Hispanics	0.000411	5.1%
Non-hispanic whites	0.000363	4.5%
Non-hispanic blacks	0.000372	4.7%
Non-hisp/non-white/non-black	0.000441	5.5%
All infants (< 1 year)	0.000784	9.8%
Nursing infants	0.000297	3.7%
Non-nursing infants	0.000968	12.1%
Children 1-6 yrs	0.000708	8.9%
Children 7-12 yrs	0.000496	6.2%
Females 13-19 (not preg or nursing)	0.000328	4.1%
Females 20+ (not preg or nursing)	0.000292	3.6%
Females 13-50 yrs	0.000329	4.1%
Females 13+ (preg/not nursing)	0.000331	4.1%
Females 13+ (nursing)	0.000397	5.0%
Males 13-19 yrs	0.000404	5.1%
Males 20+ yrs	0.000317	4.0%
Seniors 55+	0.000266	3.3%
Children 1-2 yrs	0.000715	8.9%
Children 3-5 yrs	0.000725	9.1%
Children 6-12 yrs	0.000518	6.5%
Youth 13-19 yrs	0.000367	4.6%
Adults 20-49 yrs	0.000325	4.1%
Adults 50+ yrs	0.000270	3.4%
Females 13-49 yrs	0.000312	3.9%



13544



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